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TSCA Confidential Business Information Center (7407M) EPA East - Room 6428 Attn: Section 8(e) U.S. Environmental Protection Agency 1201 Constitution Avenue, NW Washington, DC 20004-3302 Phone: (202)564-8940



Subject: Lithium Carbonate

CAS No: 554-13-2

TSCA § 8(e) FYI submission: Two Generation Reproductive Toxicity Study By Oral

Gavage In Wistar Rats

The above referenced study is being conducted, jointly sponsored by FMC Corporation's Lithium Division and Chemetall GmbH. Chemetall Foote Corp. as manufacturer of Lithium carbonate and Chemetall GmbH as sponsor of the study are affiliated companies. Both Chemetall companies are US owned by the Rockwood Specialties Group, headquartered in Princeton, NJ. The study was initiated to support product stewardship initiatives.

The European consultant hired to monitor the study brought preliminary results to the attention of product safety staff at FMC Lithium and Chemetall Foote Corp. Since these are preliminary results, we do not yet have enough data to determine if these results are clearly significant and dose related and thus meeting criteria under TSCA 8(e). Just the same, FMC and Chemetall GmbH are voluntarily submitting this information as a "for your information (FYI)" submission.

Lithium carbonate (purity: 99.6%) was given daily at doses of 2, 15 and 45 mg/kg bwt/day. Additionally there was a control group that did not receive any study material. Results of the first generation of this two generation study indicated reduced litter size and higher post implantation loss in the higher dose group (45 mg/kg bwt/day). The decline in litter size is marginal but statistically significant. The post implantation loss is not statistically significant, but is outside of the historical data for the laboratory. It is not clear whether either of these effects are dose related.

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These preliminary results being reported as an "FYI" submission related to TSCA §8(e) since these data are potentially new information on the risks of lithium carbonate. The significance of these results cannot be determined until further data are obtained and analyzed.

Please contact Helen Hatch of FMC Lithium if you have any questions about this submission or the above referenced study. She can be reached at 704-868-5309, or email at helen hatch@fmc.com

Sincerely,

Representatives of FMC Corporation, Lithium Division and Chemetall Foote Corp.:

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